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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/799,941

03/11/2004

Martha G. Welch

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8041

56949

7590

01/22/2009

WilmerHale/Columbia University

399 PARK AVENUE

NEW YORK, NY 10022

EXAMINER

KOSAR, ANDREW D

ART UNIT

PAPER NUMBER

1654

NOTIFICATION DATE

DELIVERY MODE

01/22/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

teresa.carvalho@wilmerhale.com

sharon.matthews@wilmerhale.com

michael.mathewson@wilmerhale.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/799,941	<b>Applicant(s)</b> WELCH ET AL.	
	<b>Examiner</b> ANDREW D. KOSAR	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,8,17 and 21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,8,17 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 February 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Petition Decision***

Applicant's petition under 37 CFR § 1.78, filed May 27, 2008 has been GRANTED, as set forth in the mailing of August 8, 2008.

### ***Response to Amendment/Arguments***

Applicant's amendments and arguments filed October 13, 2008 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below in original or modified form is herein withdrawn.

The declaration filed on October 13, 2008 under 37 CFR 1.131 has been considered, but is ineffective to overcome the Hollander (US 2006/0105939 A1) reference. The evidence submitted is insufficient to establish diligence from a date prior to the date of reduction to practice of the Hollander reference. Applicant provides a statement that the lab notes predate August 17, 2001, however the instant Application was filed March 11, 2004. There is no evidence of diligence between the date of asserted conception (prior to 8/17/01) and the date of filing (3/11/04). Additionally, the provisional application (60/518,389) does not show diligence during the time in question, as the priority document does not provide any disclosure of the instantly claimed composition of oxytocin with secretin, and assuming *arguendo* that such disclosure is present, it was filed more than two years after the earliest date Applicant is attempting to antedate.

Thus, the rejections is maintained below for the reasons of record.

***Priority***

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/518,389, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Specifically, there is no disclosure of the instantly claimed combination therapeutic of oxytocin with secretin.

Thus, the priority date afforded to the claims is the instant filing date of March 11, 2004.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

**Claims 1 and 17** are rejected under 35 U.S.C. 102(a) as being anticipated by WELCH

(Reference CZ; PTO-1449 5/29/07).

Welch teaches administration of S/OT composition (45-90 µg) iv or ip by Alzet pump.

The pump constitutes a kit comprising the composition.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 1, 8, 17 and 21** remain rejected under 35 U.S.C. 103(a) as being unpatentable over HOLLANDER in view of NIH News Alert, SWAIN and PIERCE, for the reasons of record and those set forth below.

The instant claims are drawn to compositions of OT/S and a kit thereof, optionally with a protease inhibitor.

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As stated previously, *In re Kerkhoven* is applicable as it is the combination of two compounds useful for the same purpose- treating autism- which are combined to make a third composition for treating autism which would flow logically from the teachings in the art.

Hollander teaches treating autism with oxytocin (claim 1) and that, “Agents suitable for use in combination therapy are any chemical compound or treatment method useful to patients with disorders associated with repetitive behaviors...” (paragraph [0046]).

NIH News Alert teaches treating autism with secretin (e.g. page 2, citing Horvath, et al.).

Swain teaches that packaging of pharmaceuticals can add to the 'bottom line' by reducing theft, counterfeiting, increasing shelf life, and improve patient compliance (page 1 of 4).

PIERCE teaches that protease inhibitors are added to protein solutions to lengthen shelf life (e.g. Table 2, page 2) by preventing cleavage of proteins.

As set forth in *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980), “It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; the idea of combining them flows logically from their having been individually taught in prior art.” Thus, because both oxytocin and secretin have been taught in the prior art as useful for treating autism, it would have been obvious to have combined the two for making a composition for the same purpose.

With regards to the kit, the examiner has interpreted 'kit' broadly to include packaging for sale. It would have been obvious at the time of the invention to have packaged the pharmaceutical composition in any packaging for the benefit of reducing theft, reducing counterfeiting and increasing shelf life of the compound, as well as for the benefit of product

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recognition during sales of the product. One would have been motivated to have packaged the pharmaceutical for the benefit of, but not limited to, increasing shelf life of the compound and to increase the product visibility. One would have had a reasonable expectation for success in packaging the pharmaceutical in order to prolong the shelf life, as packaging pharmaceuticals is widely practiced in the formulary arts in order to generate sales.

Furthermore, it would have been obvious to have added into the composition and/or kit a protease inhibitor to prevent protein degradation/cleavage during storage to increase the shelf life. One would have been motivated to have added a protease inhibitor to the composition/kit because oxytocin and secretin are both peptide compounds, susceptible to proteolysis, and to increase the shelf life of the peptides in the composition. One would have had a reasonable expectation for success in making the composition/kit with a protease inhibitor as PIERCE teaches protease inhibitors are added to prevent proteolytic cleavage of peptides during storage and to increase the shelf life.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. KNAUF (DE 4229880 A1) which teaches oxytocin used for treating autism.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Specifically, Applicant's amendment removes the limitation 'synergy', therefore the art applied (Welch) could not have been applied in the previous Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW D. KOSAR whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew D Kosar/

Primary Examiner, Art Unit 1654